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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,540	09/01/2006	Claus Frohberg	65084.000023	2168
21967 7590 06/24/2009 HUNTON & WILLIAMS LLP INTELLECTUAL PROPERTY DEPARTMENT			EXAMINER	
			PAGE, BRENT T	
1900 K STREET, N.W. SUITE 1200 WASHINGTON, DC 20006-1109		ART UNIT	PAPER NUMBER	
		1638		
			MAIL DATE	DELIVERY MODE
			06/24/2009	PAPER

## Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary  The MAILING DATE of this communication appears on the Period for Reply  A SHORTENED STATUTORY PERIOD FOR REPLY IS SET WHICHEVER IS LONGER, FROM THE MAILING DATE OF T	PAGE  TO EXPIRE 3 MONTH(S) HIS COMMUNICATION. vent, however, may a reply be timely will expire SIX (6) MONTHS from the plication to become ABANDONED (3)	OR THIRTY (30) DAYS, filed mailing date of this communication.					
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	HIS COMMUNICATION. vent, however, may a reply be timely will expire SIX (6) MONTHS from the plication to become ABANDONED (3)	filed mailing date of this communication.					
<ul> <li>Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no eafter SIX (6) MONTHS from the mailing date of this communication.</li> <li>If NO period for reply is specified above, the maximum statutory period will apply and Failure to reply within the set or extended period for reply will, by statute, cause the appropriate Any reply received by the Office later than three months after the mailing date of this cearned patent term adjustment. See 37 CFR 1.704(b).</li> </ul>							
Status							
1)⊠ Responsive to communication(s) filed on <u>04/30/2009</u> .							
2a) This action is <b>FINAL</b> . 2b) This action is	non-final						
	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims	<b>,</b>						
	tion						
4) Claim(s) <u>1-23,25-27 and 29</u> is/are pending in the applica	4a) Of the above claim(s) <u>20-23 and 25-27</u> is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>1-19 and 29</u> is/are rejected.							
7) Claim(s) <u>1-19 and 29</u> is/are rejected. 7) Claim(s) is/are objected to.							
· · · · · · · · · · · · · · · · · · ·	7)□ Claim(s) is/are objected to: 8)□ Claim(s) are subject to restriction and/or election requirement.						
o) Claim(s) are subject to restriction and/or election requirement.							
Application Papers							
9)⊠ The specification is objected to by the Examiner.							
10)⊠ The drawing(s) filed on <u>01 September 2006</u> is/are: a)⊠ accepted or b)⊡ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s)	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. § 119							
<ul> <li>12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) ☒ All b) ☐ Some * c) ☐ None of:</li> <li>1.☐ Certified copies of the priority documents have been received.</li> <li>2.☐ Certified copies of the priority documents have been received in Application No</li> <li>3.☒ Copies of the certified copies of the priority documents have been received in this National Stage</li> </ul>							
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.							
Attachment(s)  1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 9/2006, 11/2006.	4) Interview Summary (PT Paper No(s)/Mail Date. 5) Notice of Informal Pate 6) Other:	·					

### **DETAILED ACTION**

#### Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 04/30/2009 is acknowledged. The traversal is on the ground(s) that the technical feature linking the inventions is products and methods related to the OK1 protein and not a phosphoglucan gene or protein.

This is not persuasive because the phosphorylation of starch by the OK1 protein depends on prior phosphorylation by the R1 protein, and therefore art taught by Ritte et al is clearly related to the OK1 protein and falls under the category of "products and methods related to an OK1 protein" (see page 3 of response).

Applicants also urge that the R1 protein and OK1 protein are distinct.

This is not persuasive because for example claim 1, and indeed many claims of the instant claim set, are not limited to nucleic acids encoding the OK1 protein, but rather recite any genetic modification that increases the activity of the OK1 protein. Because the OK1 protein is only active when starch is phosphorylated by R1, an increase in the R1 protein, as taught by Ritte, would lead to an increase in activity of the OK1 protein, and therefore, meets the limitations of this particular feature of the invention. Regardless, as cited below, Kikuchi et al do teach a nucleic acid encoding the OK1 protein, and therefore the technical feature linking the inventions whether it is nucleic acid sequences encoding the OK1 protein, nucleic acid sequences increasing the activity of the OK1 protein, or phosphoglucan genes or proteins, are all considered not to be an

advancement over the prior art as discussed in the restriction requirement mailed out on 04/30/2009 as well as the reasons stated above.

The requirement is still deemed proper and is therefore made FINAL.

Claims 20-23 and 25-27 are hereby withdrawn by the Examiner as being drawn to non-elected subject matter. Claims 1-19 and 29 are examined herein on the merits.

## Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. There are 10 embedded hyperlinks, 2 each in paragraphs 103 and 307 of the specification, 1 in paragraph 104, 1 in paragraph 416, 1 in paragraph 164, and 3 in paragraph 347 of the specification. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

# Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites in part a "wherein the genetic modification increases the activity of at least one OK1 protein in comparison with corresponding wild type

plant cells that have not been genetically modified". However, claim 12 depends from claim 6, which is a plant comprising one or more plant cells according to claim 1 which recites "A genetically modified plant cell, which has a reduced activity of at least one OK1 protein…". It is unclear whether Applicant intended to claim an increase in OK1 protein activity or a reduced OK1 protein activity.

Because the rest of the claims including claims depending from claim 12 all recite a reduced activity, it is believed that claim 12 is a typographical error. On that basis, the claim will be examined in light of this perceived error. Clarification is requested because it would be unclear how one would go about manufacturing a genetically modified plant with an increased OK1 protein activity when comprising one or more cells with a reduced OK1 protein activity.

## Claim Rejections - 35 USC § 112-written description

Claims 12-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 12 is drawn to a method of manufacturing a genetically modified plant according to claim 6 comprising: genetically modifying a plant cell, wherein the genetic modification increases the activity of at least one OK1 protein.

However, the plant according to claim 6 comprises cells which have a "reduced activity of at least one OK1 protein". There is no support in the specification for a

method of producing a plant with reduced OK1 protein activity by a genetic modification that increases the activity of OK1, literal or otherwise, and the claim is therefore directed to New Matter. Applicant must delete the New Matter from the claim. Dependent claims 13-15 are rejected for containing the same limitations as claim 12.

### Claim Rejections - 35 USC § 112-enablement

Claims 12-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 12 is drawn to a method of manufacturing a genetically modified plant according to claim 6 comprising: genetically modifying a plant cell, wherein the genetic modification increases the activity of at least one OK1 protein.

However, the plant according to claim 6 comprises cells which have a "reduced activity of at least one OK1 protein". There is no guidance in the specification that would enable one of skill in the art to practice a method of producing a plant with reduced OK1 protein activity by a genetic modification that increases the activity of OK1. There is literally no mention of such a method that uses a construct that which in one plant reduces the activity of the OK1 protein but wherein the genetic modification leads to an increase in the activity of the OK1 protein. Dependent claims 13-15 are rejected for containing the same limitations as claim 12.

## Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-2, 4-19, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Frohberg (US Patent 6521816) in light of Ritte et al (2006 FEBS Letters 580:4872-4876).

The claims are directed to a genetically modified plant cell which exhibits reduced activity in at least one OK1 protein comprising at least one foreign nucleic acid molecule, wherein the plant is maize or wheat, propagation material from said plant, a harvestable part of said plant and a method of manufacturing a genetically modified plant.

Frohberg teaches the transformation of a host cell with an isolated nucleic acid that encodes an R1 protein, wherein the starch of the cell is modified (see claims 13-28 and 55-66 for example) in maize (see claim 8, for example and specification indicating it as a plant for use with the invention) and wherein the OK1 protein is inherently reduced in light of Ritte et al who teaches that the activity of PWD (OK1) is strictly dependent on phosphorylation of the starch by

GWD (R1) and that GWD phosphorylated c-6 while OK1 phosphorylates c-3, and therefore the reduction in phosphorylated starch would reduce the activity of OK1 (see page 4875 first paragraph under discussion, for example). Regarding claim 12, it is believed that the limitation "wherein the genetic modification increases the activity of at least one OK1 protein" is a typographical error since the claim depends from claim 6 which depends from claim 1 in which the genetically modified plant cell has a "reduced activity of at least one OK1 protein". If this is not a typographical error, the current rejection as written does not apply to claims 12-15, however, based on the repeated reference in claim 14 of a reduced expression, claims 12-15 are being examined with regard to prior art with the understanding that the limitation in claim 12 was meant to refer to a reduction in expression. It is further noted that if an increase was intended, that the claims taught by Frohberg, particularly claims 1-9 would also inherently lead to an increase in OK1 activity since there would be increased substrate.

Claims 1-7, 9-11, 16-19, and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Kikuchi et al (US20060123505A1, filed May 29, 2003).

The claims are directed to a genetically modified plant cell which exhibits reduced activity in at least one OK1 protein comprising at least one foreign nucleic acid molecule, wherein a modified starch is synthesized, propagation material from said plant, a harvestable part of said plant and a method of manufacturing a genetically modified plant, wherein the foreign nucleic acid encodes an OK1 protein, and a host cell, vector, composition, plant and harvestable parts all comprising said foreign nucleic acid molecule.

Kikuchi et al teach the transformation of a host cell and regeneration of a plant with SEQ ID NO:22133 which encodes the OK1 protein or PWD from rice, a vector comprising the sequence and plant parts therefrom, wherein that starch properties are inherent in the expression of the foreign nucleic acid and wherein the constructs are antisense, ribozyme, RNAi, or co-suppression constructs (see claims 1-26, for example.

## **Double Patenting**

Claim 12 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of copending Application No. 10591428. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim the same method and the same method steps. The only difference is the starting material cells, but both claim a method of manufacturing a genetically modified plant comprising genetically modifying a plant cell wherein the genetic modification increases the activity of at least one OK1 protein.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Brent T Page

/Anne Marie Grunberg/ Supervisory Patent Examiner, Art Unit 1638